

REMARKS/ARGUMENTS

This is in response to the Office Action mailed January 10, 2006. Claims 1, 50, and 61 have been amended. Support for amendments to claims 1, 50 and 61 can be found throughout the originally filed application, e.g., page 9, lines 4-6. No new matter is introduced and these are not intended to be narrowing amendments. Independent claim 1 and its dependent claims 5-6, 27-49 and 52-53, independent claim 50 and its dependent claims 51, 54-55 and 57-60, and independent claim 61 and its dependent claims 62-64, are currently pending and at issue.

Claim Rejections - 35 U.S.C. §112, first paragraph

The Examiner has maintained rejections from the previous office action directed to claims 1, 5-6, and 27-64, under 35 U.S.C. §112, first paragraph, based on an alleged admission made by one of the inventors during an interview. The Examiner asserts that the specification, while enabling for those on a low-calorie diet and who are not already consuming three servings of dairy, does not reasonably provide enablement for one on any diet and consuming any amount of dairy. Moreover, the Examiner asserts that the Applicants' previous arguments made in response to this rejection provide no authority for the premise that the cited interview is not admissible because it is hearsay. As to authority, hearsay is inherently unreliable, as reflected in Federal Rules of Evidence, e.g., Rules 801-806, which provide only certain exceptions to the rule against admitting hearsay. Moreover, the Applicants respectfully request the Examiner to provide authority for categorizing the interview as an inventor admission. The only place that Applicant can find in the MPEP that addresses Applicant admissions are in sections 706.02(c), 2129, and 2133.03(c). The alleged admission does not fall within any of these sections.

The claims recite restricting caloric intake and administering calcium in an amount of at

least about 773 mg per day or above about 400 mg per day or at least about 57 servings of dairy per month (equivalent to at least about two servings a day of dairy). The Examiner has not provided reasons why these claims are not enablingly described in the specification. The Applicants respectfully request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 1, 5-6, and 27-64, under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because in claims 1, 50, and 61, the term "restricted caloric diet" is vague and subjective.

The Applicants disagree with the Examiner's characterization that the term "restricted caloric diet" is vague. This term is clear as set forth in the claims and specification and as would be understood by a one skilled in the art, such as a nutritional expert, or even layman, such as the common dieter. As set forth in the specification, the caloric intake of an individual may be unmodified or ad lib and it may be desirable to reduce the caloric intake of the individual as part of the dietary plan (e.g., page 9, lines 3-9). Ad lib is defined as "without restraint or limit" (Merriam-Webster Online Dictionary <<http://www.m-w.com/cgi-bin/dictionary>> visited March 10, 2006). It is commonly understood in the field of nutrition that there are two practices of energy intake, e.g., food, drinks or calories, either (1) ad lib or (2) restricted. Ad lib is a commonly used term that is understood to be the unrestricted intake of food or calories available to the point of satisfaction. Restricted diets may include a variety of diets, including for example, restricting caloric intake. As is readily apparent from the specification, the restriction of unmodified or ad

lib caloric intake may be slight or more extensive based on whether the individual is maintaining or reducing body weight.

To facilitate prosecution, the Applicants have amended the independent claims to recite a restricted caloric intake below ad lib. This is not a narrowing amendment because the scope of the claims is the same as without the clarifying language.

Applicants respectfully request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a)

The Examiner has rejected the claims under U.S.C. § 103(a) as being unpatentable over (1) Metz et al (AJH 1:58-60 1988), (2) Skinner (Scan J Nutr 2/99 suppl 34 p. 45S), and (3) Summerbell (BMJ 317 1998 p. 1478-89), in view of knowledge that allegedly can be obtained by routine experimentation or is well known to one of ordinary skill in the art.

In each of the three rejections, the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143. Each cited reference does not teach or expressly or impliedly suggest any of the limitations set forth in the present claims. There is no motivation to combine the references with other knowledge. There would not be a reasonable expectation of success. Moreover, it is inappropriate for the Examiner to take official notice that the other elements can be readily obtained by routine experimentation or are generally known to one of ordinary skill in the art, or to modify the references to reach the claimed invention.

In addition, the Applicants previously submitted evidence showing the present invention's unexpected results, which has led to a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention leading to significant recognition and commercial success.

The Examiner rejected claims 1, 5-6, and 27-64 under U.S.C. § 103(a) as being unpatentable over Metz et al (AJH 1:58-60 1988). The Examiner asserts that Metz teaches a reduction in body fat in rats consuming higher diets of calcium and that it would have been obvious to one of ordinary skill in to formulate a high calcium diet for humans to achieve the beneficial effect of a reduction in body fat content in view of the Metz results.

Currently independent claims 1, 50 and 61 are directed to methods for administering therapeutically effective or sufficient amounts of calcium to induce weight loss in an individual, wherein the individual is further restricting caloric intake below ad lib and wherein the calcium is in an amount of at least about 773 mg or above about 400 mg per day or contained in dairy products administered in an amount of at least about 57 servings of dairy per month.

The present invention is distinct from Metz, which does not disclose, teach or suggest any of the elements of independent claims 1, 50, or 61. Metz is directed to a hypothesis that modification of body fat can be accomplished by the simultaneous administration of calcium with sodium. In the introduction, Metz teaches that some reports indicate supplementation of both dietary calcium and sodium results in a beneficial interaction between these two cations. The experiments were conducted on rats in three groups receiving: (1) high calcium/ high sodium, (2) moderate calcium/ moderate sodium and (3) low calcium/ low sodium. The results show that groups receiving higher amounts of calcium with sodium resulted in body weight reductions.

As set forth in the discussion, Metz teaches that "[t]o date, Ca²⁺ intervention trials in humans with hypertension have not noted significant reduction in body weight with Ca²⁺ supplementation." Metz further teaches that: "[d]ietary sodium was simultaneously modified in this study, as earlier investigations had demonstrated that calcium effects on blood pressure were,

in part, sodium-dependent. Thus, concurrent manipulations of Ca^{2+} and Na^+ were utilized in this study." Metz concludes that "current results confirm that body fat and weight can be favorably modified by increasing the dietary content of both calcium and sodium."

Metz uses both "calcium and sodium" to show body weight changes. Metz does not isolate calcium from sodium and does not show or suggest that specifically only calcium is responsible for the weight benefits. Nor is there motivation to separate the effects of calcium from sodium because that was not part of the hypothesis of Metz, relating to synergistic effects of calcium with sodium on body fat and weight. To the contrary, the present invention specifies calcium alone, without sodium, to induce weight loss. Indeed, the use of two elements to affect body weight as in Metz, in contrast to the omission of one, while still retaining the function of weight loss as in the present invention, supports unobviousness of the present invention. See MPEP § 2144.04 ("the omission of an element and retention of its function is an indicia of unobviousness").

Therefore, Metz does not teach or suggest the use of calcium to induce weight loss as set forth in the present invention.

The Examiner further asserts that as to the particular dosage frequency, amount and vehicle, optimum parameters may be obtained by routine experimentation. This is incorrect because even with hindsight analysis, it would take extensive experimentation to obtain the dosage frequency, amount and vehicle as required by the present invention. The specification reflects extensive experimentation to show the effects of calcium and dairy to induce weight loss. For example, Example 1 involved at least six weeks of administration and Example 2 involved at least two six-week stages, all of which were followed by extensive analysis to arrive at the

invention. This is evidence that undue experimentation would have been required.

Also, the Examiner contends that one of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes. Finally, the Examiner states that the particular claimed foods are known to contain calcium and the claimed supplements are also well known, even to the layman. However, one would not be motivated to combine the teaching of Metz with these dosages because such foods high in calcium, such as dairy, were not previously recognized and would have been unexpected at the time the application was filed to induce weight loss.

Moreover, the Examiner inappropriately takes official notice without documentary evidence to support the above conclusions. Official notice unsupported by documentary evidence should not be taken by the Examiner because the facts are not capable of instant and unquestionable demonstration as being well-known, and they are in dispute (MPEP § 2144.03). As demonstrated by evidence submitted by the Applicant, as discussed below, the results of this invention, at the time the application was filed, were unexpected. It would not have been commonly known to use dietary calcium or dairy to induce weight loss. Therefore, official notice as set forth by the Examiner that the claimed invention is obvious over allegedly well known elements is not permissible under these circumstances.

Claims 1, 5-6, and 27-64 were rejected under U.S.C. § 103(a) as being unpatentable over Skinner (Scan J Nutr 2/99 suppl 34 p. 45S). The Examiner contends that Skinner teaches that children's body mass is moderated by dietary calcium and that it would have been obvious to one of ordinary skill to formulate a high calcium diet for children to achieve the beneficial effect of a reduction in body fat content in view of the Skinner results.

The present invention is distinct from Skinner, which does not disclose, teach or suggest the elements of independent claims 1, 50, or 61. Skinner discloses that "[i]n a longitudinal study of healthy children (n=72), three days of food intake were collected at each of six interviews (ages 24 to 60 month) and the longitudinal intakes were determined for various nutrients..." This was done "to determine the role of various nutrients in fat mass." Skinner mentions several variables, including calcium, protein, fat and monounsaturated fat and concludes that "calcium and monounsaturated fat were negatively related to children's fat mass."

However, Skinner does not present experiments using calcium or dairy alone, nor was it a weight loss study. The results of Skinner are not based on experiments designed to isolate the effectiveness of calcium or dairy to induce weight loss as set forth in the present invention. Instead, Skinner observed relationships between intake of various nutrients by children and their fat mass, not weight loss. The children's fat mass could have been affected by a number of variants, e.g., the natural growth of the child based on their genetic makeup, physical activity, or other dietary habits. Moreover, energy was not restricted in these growing children. Growing children are expected to gain weight, not lose weight. One could not extrapolate from these observations a method of administering calcium or dairy alone to induce weight loss in a subject.

The reference does not suggest that calcium or dairy alone is inducing weight loss. Rather the association with monounsaturated fat means the results would not lead one skilled in the art to conclude that calcium or dairy alone can be used to induce weight loss. At the time the application was filed this would have been contrary to commonly known perceptions as discussed below.

The Examiner further asserts that as to the particular dosage frequency, amount and

vehicle, optimum parameters may be obtained by routine experimentation. Also, the Examiner states that the particular claimed foods are known to contain calcium and the claimed supplements are also well known, even to the layman.

As noted above, these points are incorrect, irrelevant to the pending claims and/or it was inappropriate for the Examiner to take official notice without documentary evidence to support these conclusions.

Claims 1, 5-6, and 27-64 were rejected under U.S.C. § 103(a) as being unpatentable over Summerbell (BMJ 317 1998 p. 1478-89). The Examiner asserts that Summerbell allegedly teaches weight loss in obese patients on a diet comprising milk or yogurt and that it would have been obvious to one of ordinary skill in to formulate a high calcium diet for obese patients to achieve the beneficial effect of a reduction in body fat content in view of the Summerbell.

Applicants contend that the present invention is distinct from Summberbell, which does not disclose, teach or suggest any of the elements of independent claims 1, 50, or 61.

As set forth in the introduction, Summerbell tests diets with high compliance and hence good for weight loss. The study in Summerbell was designed to test the hypothesis that prescription of a simple and novel diet would result in higher levels of compliance and weight loss. In fact, Summerbell associates higher weight loss for the milk groups diet because that diet is "simple but much less boring and patients were more likely to comply with it" than with the conventional diet. Indeed, Summerbell is "not advocating milk only as a general long term reducing diet for obese outpatients, because in the long term it will cease to be novel and compliance will fall." Summerbell concludes that "[p]robably the best strategy is to rotate diets..." This statement would lead one away from the teaching of the present invention, which

involves the use of sufficient amounts of dietary calcium or dairy, e.g., daily for a month or more. The point to extrapolate from Summerbell is that one could use any type of food regimen or diet so long as it is simple and less boring to ensure compliance. Nowhere in Summerbell is it disclosed that calcium or dairy alone directly induces weight loss, as opposed to indirectly causing a dieter to lose weight by reducing overall caloric intake.

The Examiner further asserts that as to the particular dosage frequency, amount and vehicle, optimum parameters may be obtained by routine experimentation. Also, the Examiner states that the particular claimed non-dairy foods are known to contain calcium and the claimed supplements are also well known, even to the layman.

As noted above, these points are incorrect, irrelevant to the pending claims and/or it was inappropriate for the Examiner to take official notice without documentary evidence to support these conclusions.

The present claims should not be deemed obvious in light of any of the cited references, Metz, Skinner or Summerbell, because none of the cited references expressly or impliedly teach, disclose or suggest, any of the limitations set forth in present claims 1, 50 and 61. Moreover, there is no motivation to use the cited knowledge, nor would combining the cited references or knowledge teach the claimed methods of administering therapeutically effective or sufficient amounts of calcium or dairy to induce weight loss in an individual, wherein the individual is further restricting caloric intake and wherein the calcium is in an amount of at least about 773 mg or above about 400 mg per day or contained in dairy products administered in an amount of at least about 57 servings of dairy per month.

Also, Applicants have submitted evidence showing that due to the unexpected results of

Dr. Zemel's work, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention. The evidence shows that the invention has achieved considerable public recognition and commercial success.

Therefore, Metz, Skinner, or Summerbell, either alone or in combination with other knowledge, do not disclose, teach or suggest the claimed invention as set forth in claims 1, 50, or 61 or dependent claims 5-6, 27-60 and 62-64. These include additional limitations distinguishing them from the cited references, e.g., specific dosage and products.

Claims 1, 5, 6, and 27-64 are patentable because none of the cited references or material disclose, teach or suggest the present invention.

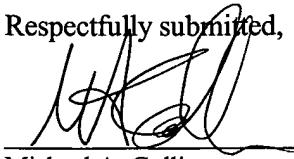
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1, 5, 6, and 27-64 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

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